REMARKS

Claim Rejections - 35 USC § 112

Claim(s) 1-7 are pending in the application. Claims 1-7 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicant respectfully traverses the rejection of claims in view of the arguments and amendments herein.

The office action states that the method of claim 1 does not specify just what property(ies) of the probe is/are detection of the probe's presence. It goes on to say that with the total amount of probe being present throughout the assay, that one of skill in the art would be detecting probe whether or not any target was present, and that this detection of probe would then, erroneously, be construed as indicating some movement of the (unbound) molecular motor as being present, and thusly, and erroneously, reach the conclusion that the target nucleic acid was also present.

Applicant respectfully traverses this rejection by amending claim 1 to clarify the property(ies) of the probe. Specifically, claim 1 has been amended to specify that movement of the molecular motor is indicated by **regularly** changing color as distinguished from the randomness of non-motor induced rotation such as Brownian motion.

The office action further states that for purposes of examination, claim 1 has also been construed as requiring ligation of first and second target-specific nucleic acids together irrespective of their having hybridized, or not hybridized, to the target nucleic acid. The office action goes on to note: "While claim 1 does specify that the first and second target nucleic acids will hybridize to target only if the target is present, no requirement of a precondition of hybridization to target is required for the step ligating first and second target-specific nucleic acids."

Applicant respectfully traverses this rejection by amending claim 1 to clarify the property(ies) of the probe. Specifically, claim 1 has been amended to specify that "upon hybridization to the target nucleic acid, ligating the first and second target-specific nucleic acids together…"

The office action acknowledges applicant's previous amendment to claim 1 to recite, "The molecular motor comprises a biological or synthetic molecule capable of induced translational or rotational movements that are capable of detection." The office action goes on to note: "that the translational or rotational movements are not specified as being that which is being detected. Further, with all members of the reaction in solution, it stands to reason that said members of the reaction, including the probe, would be freely moving about, be it Brownian movement and/or response to thermal currents in the solution and therein exhibiting some form of translational or rotational movement. Indeed, even if the target nucleic acid were immobilized on one end, the unbound portion would still be free to move about- irrespective of the molecular motor and probe."

Applicant respectfully traverses this rejection by amending claim 1 to clarify the property(ies) of the probe. Specifically, claim 1 has been amended to specify that movement of the molecular motor is indicated by **regularly** changing color as distinguished from the randomness of non-motor induced rotation such as Brownian motion.

The office action further states that for purposes of examination, the claimed method has been construed as encompassing the simultaneous detection of multiple target nucleic acids. The claims have not been construed as requiring the use of different molecular motors and/or different probes. Accordingly, it would not be possible to determine which, if any, of an assortment of different target nucleic acid(s) is/are present in any given sample.

Applicant respectfully traverses this rejection by amending claim 1 to clarify the property(ies) of the probe. Specifically, claim 1 has been amended to specify that observation of ATP-dependent rotation of different colored nanorods indicates the presence of the corresponding target each having its **unique** probe attachment or **different** motors causing different specific motor-induced motion so as to allow determination of an assortment of different target nucleic acid(s) is/are present in any given sample.

The office action further states that for purposes of examination, claim 1 has been construed as requiring the use of a first and second "target specific nucleic acid." However, the aspect that the first and second target-specific nucleic acids be "specific" for *only* the target(s) of interest has not been read into the claims. Rather, the claims have been construed as encompassing a nucleic acids that are complementary to a region that is found within the target- and may also be found in some other nucleic acids as well.

Applicant respectfully traverses this rejection by amending claim 1 to clarify that the first and second target-specific nucleic acids are "specific" for *only* the target(s) of interest. Specifically, claim 1 has been amended to add a limitation "wherein the first and second target-specific nucleic acids are specific only for a selected one of the at least one target nucleic acid of interest." Thus the limitation is now part of claim 1 traversing the rejection.

The office action further states that Claims 1-7 are not enabled by the specification as the specification does not disclose a representative number of species of first and second target-specific nucleic acid that hybridize "directly adjacent to each other." In support of this position, it is noted that the clamed method encompasses the detection of any target nucleic acid, be it from any animal, plant, bacteria, virus, artificial chromosome, etc. The specification, however, discloses but 4 sequences, which are all described in the Sequence Listing as being "Synthetic Oligonucleotide" and range in length of 25-42 nucleotides in length.

Applicant respectfully traverses this rejection. To satisfy the written description requirement of the first paragraph of 35 U.S.C. § 112, a disclosure need only describe a claimed invention in a manner sufficient to reasonably convey to those skilled in the relevant art that Applicant possessed the claimed invention. This possession may be shown in any number of ways and an Applicant need not describe every claim feature exactly. (MPEP §2163 (emphasis added)). Rather, all that is required is "reasonable clarity." Also, original subject matter enjoys a "strong presumption" of compliance with the written description requirement. (MPEP §§ 2163 (I)(A), 2163(II)(A), 2163(II)(A)(3)(a)).

Initially, it is important to recognize that the rejected subject matter is original to this application. Thus, the Office must overcome a strong presumption that the rejected claims comply with the written description requirement. This is because a description as originally filed is presumed to be adequate, unless or until evidence or reasoning to the contrary has been presented by the examiner sufficient to rebut the presumption. (MPEP § 2163.04).

> What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species. Cf. *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). (MPEP § 2163).

In the present application one of skill in the art would recognize that the examples provided are more than adequate to enable claims 1-7. This is shown by the attached references which show that one skilled in the art would have no difficulty in substituting other sequences to use the claimed method for the detection of any target nucleic acid, be it from any animal, plant, bacteria, virus, artificial chromosome, etc.

The ability to identify unique living organisms including plants, bacteria, and animals has become standardized in the past few years. This process is known as DNA barcoding that involves determining the sequence of a standard region of DNA as a tool for species identification. The standard region of DNA sequenced is typically 40 base pairs in length.

For plants, the standard chosen sequences originate in the matK gene, rbcL gene, rpoB gene, and rpoC1 gene. In addition DNA sequences that exist in the spacer region between the genes atpF-atpH spacer, psbK-psbI spacer, trnH-psbA spacer. Details concerning these DNA sequences can be found in Hollingsworth et al. (2009), Fazekas et al. (2009), and Kress and Erickson (2007). Hollingsworth et al. (2009) reported DNA sequences from these genes and spacers for 445 angiosperms, 38 gymnosperms, and 67 cryptogam species. To date, an inquiry of the NCBI data base yielded 64,879 DNA sequences from various plants and photosynthetic bacteria for rbcL (the large subunit of the RuBP carboxylase enzyme also known as RuBisCO). These sequences are readily accessed at the NCBI web site (http://www.ncbi.nlm.nih.gov/nuccore) searching under nucleotide and rbcL.

Standard barcoding has also been established for all aerobic organisms including animals, plants and bacteria based on the COI gene that encodes the cytochrome oxidase I subunit. To date, an inquiry of the NCBI data base for the COI gene returned DNA sequences for 438,229 different species. Details concerning the barcoding sequences and how to submit, access and compare these COI DNA sequences can be found at the links http://www.ncbi.nlm.nih.gov/genbank/barcode.html and http://www.boldsystems.org/views/login.php. There is a huge data base on this.

REFERENCES

Hollingsworth, P. M., et al. (2009) "A DNA barcode for land plants", Proc. Natl. Acad. Sci. (USA) 106, 12794-12797

Fazekas, A. J. et al. (2009) "Multiple multilocus DNA Barcodes from the Plastid Genome Discriminate Plant Species Equally Well", PLoS ONE, 3, e2802

Kress, W. J. and Erickson, D.L. (2007) "A Two-Locus Global DNA Barcode for Land Plants: The Coding rbcL Gene complements the non-coding trnH-psbA Spacer Region", PLoS ONE, 1, e508

The office action further states that claim 1 is indefinite with respect to what constitutes a "molecular motor." While applicant has amended claim 1 so to recite that "the molecular motor comprises a biological or synthetic molecule capable of induced translational or rotational movements that are capable of detection." Such a limitation seemingly encompasses any and all manner of molecules as any form of matter can be forced to move either translationally or rotationally. With the claim specifying that the molecule can be "synthetic," such does not define the population of molecules such that one would be readily able to determine which compounds is/are encompassed by the claims. Claims 2-7, which depend from claim 1, fail to overcome this issue and are similarly rejected.

Applicant respectfully traverses this rejection. Claim 1 has been amended to specify that the molecular motor "consists essentially of a biological or synthetic molecule capable of induced translational or rotational movements that are capable of detection." Claim 3 has been amended to "The method of claim 1 wherein the molecular motor consists essentially of ~~comprises~~ an F1-ATPase." Claim 3 is now believed to be allowable.

The office action further states that claim 1 remains indefinite with respect to what constitutes a "detection probe." Applicant respectfully traverses this rejection. Claim 1 has been amended to clarify what constitutes a "detection probe" as follows: "...a detection probe consisting essentially of a metal nanorod." Thus the term is now clearly defined and is in compliance with § 112.

Claims 5-7 are indefinite with respect to what constitutes the metes and bounds of "metal nanorod." Applicant respectfully traverses this rejection and notes that the US PTO has issued at least 60 patents that include metal nanorods in the claims alone. Thus the term is well understood by the Patent Office. These patents go back to, for example, US Patent No. 5,897,945 issued April 27, 1999 is entitled "METAL OXIDE NANORODS."

Further metal nanorods are commercially available such as through Nanostructured & Amorphous Materials, Inc. of Houston, TX 77084, and Meliorum Technologies, Inc., Rochester, NY. Thus metal nanorods are well understood in the art and require no further definition in the claims.

Reconsideration and further examination is respectfully requested.

Applicants have made a diligent effort to place the claims in condition for allowance. However, should there remain unresolved issues that require adverse action, it is respectfully requested that the Examiner telephone George A. Leone, Applicants' Attorney at 253-682-0246 so that such issues may be resolved as expeditiously as possible.

For these reasons, and in view of the above amendments, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,

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